

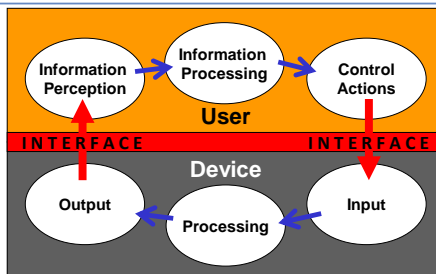
Human Factors at FDA's Center for Devices and Radiological Health (CDRH)

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FDA /CDRH / ODE

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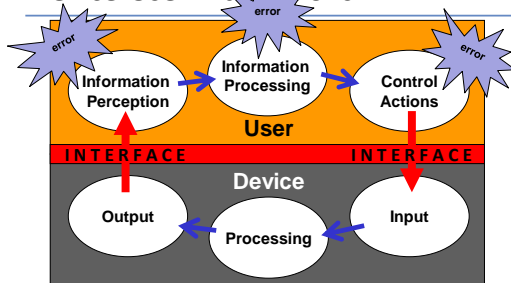
Device-User Interactions



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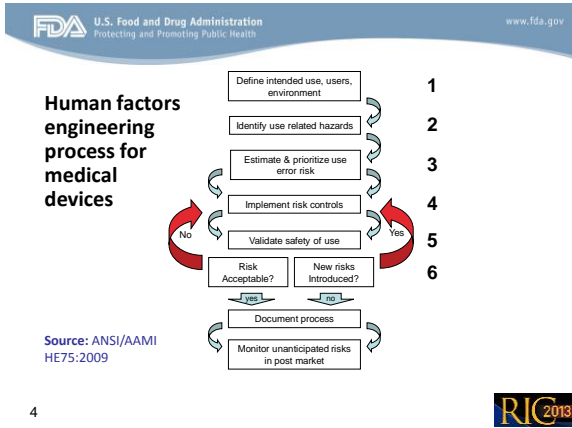


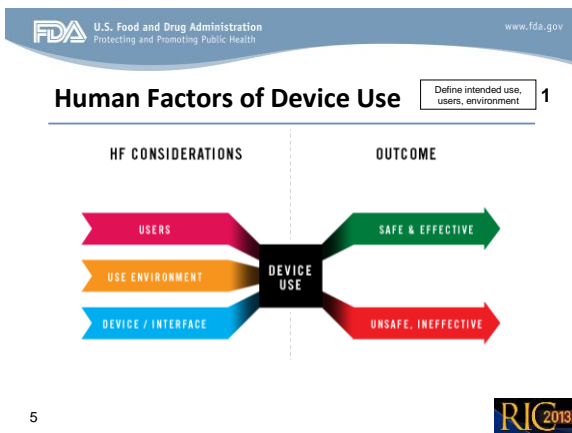
Device-User Interactions



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Preliminary Analyses

Two ways to discover use-related hazards:

- 1. Apply analytical techniques**
 - Apply variety of techniques to identify use-related hazards and risks
 - Can be difficult to anticipate all hazards
- 2. Conduct user-based evaluations**
 - Conduct hands-on testing to identify unanticipated hazards
 - Sometimes called "Usability Testing" or "Use Testing" or "User Testing" or "Formative" Evaluations

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Risk Control

Implement risk controls 4

- **Develop risk mitigation strategies as needed:**
 - Modify the interface design, user instructions, and/or training to address the problems found
- **Re-test to assess whether mitigation strategies:**
 - Effectively reduced the known risks and
 - Did not introduce any new risks
- **Residual risk can be acceptable if it is:**
 - Reasonably limited, difficult to eliminate or further reduce, and outweighed by the device's benefits

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Human Factors Validation

Validate safety of use 5

- **Demonstrates and provides evidence that a medical device, as designed, can be used safely and effectively:**
 - By people who are representative of the intended users
 - Under expected use conditions
 - For core tasks and safety-critical tasks

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Human Factors Validation Testing

- **Test populations**
 - Represent all major intended user groups
 - Healthcare professionals, pharmacists, patients, etc.
 - Pediatric & geriatric populations need careful consideration
- **Device testing conditions**
 - Use finalized design of device, packaging, and labeling
 - Provide realistic training
 - Present device within the typical context of use
 - Incorporate expected use conditions that might affect user interactions with the device
 - Allow realistic device-user interactions

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Human Factors Validation Data

- **Objective (performance) data:**
 - Facilitator observes and notes all use errors, failures and difficulties, including details about performance, e.g.:
 - Task success or failure, use error, close call, reference to instructions for use, need for assistance, evidence of difficulty or confusion, unsolicited comments
- **Subjective (narrative comment) data:**
 - Discuss user performance after use, particularly regarding reasons for any core task and critical task errors, failures and difficulties
 - Solicit participant feedback on design of device, packaging, labeling and training

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Validation Data Analysis

Risk
Acceptable?

New risks
Introduced?

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- **Analyze all use errors and failures**
 - Determine root cause and potential clinical consequences
 - Determine need to modify device, labeling, or training
 - Identify true residual risks
- **Use errors/failures are not of equal importance**
 - Some errors might be frequent but inconsequential
 - Some errors might be rare but reveal a hazardous design deficiency that was not previously recognized

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FDA Expectations for HF Data

- **Conduct a comprehensive hazard/risk assessment, including all use-related hazards/risks**
- **Identify and mitigate serious hazards/risks**
 - Identify use-related hazards/risks that could result in serious harm to the user or patient
- **Conduct human factors/usability validation testing**
 - Particularly on any strategies implemented to mitigate serious use-related hazards/risks
- **Compare device's residual risks to its benefits**

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Key Standards & FDA Guidance Docs

- **ANSI/AAMI/ISO 14971: 2007**, *Medical devices – Application of risk management to medical devices*
- **IEC 62366: 2007**, *Medical devices – Application of usability engineering to medical devices*
- **FDA (2000)**: *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*
- **FDA (2010, draft)**: *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*

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